

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE
MEDICINE

Plaintiff,

v.

IMSTEM BIOTECHNOLOGY, INC., XIAOFANG
WANG, and REN-HE XU,

Defendants.

C.A. NO. 1:17-cv-12239-ADB

**ASTELLAS' OPPOSITION TO DEFENDANTS' ATTEMPT TO RAISE A
LAST MINUTE, NEW, UNPLED AFFIRMATIVE DEFENSE**

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Plaintiff Astellas Institute for Regenerative Medicine (“Astellas”) opposes Defendants ImStem Biotechnology, Inc., Xiaofang Wang, and Ren-He Xu’s attempt to raise a new, unpled affirmative defense at the last minute.¹

I. INTRODUCTION

This case has been going on for nearly three years. Last week, just over a month before trial, Defendants slipped a brand new affirmative defense—preemption—into their Trial Memorandum. They did so without seeking leave of Court. And they did so despite that they could have raised it any time in the last three years, and even admitted at last week’s Pretrial Conference that they have been considering the defense for over eight months.² Instead, they remained mum, springing the defense on Astellas and the Court at the last minute, depriving Astellas of any opportunity to address the defense on summary judgment or in its trial briefs.³

There is no conceivable justification for Defendants’ delay, much less the good cause required by the rules. For these reasons, and those below, Defendants should be precluded from presenting their last-minute preemption defense.

¹ Astellas was unsure what to style this paper, since it is *Defendants* who are trying to add a brand new affirmative defense at the last minute, and in reality they should be moving to amend their answer. Presumably, the reason they did not do so is because there was no conceivable justification for their delay, much less one that would constitute good cause, as explained herein. Following the Court’s lead, Astellas styled this as an opposition (*see* Dkt. 224).

² The transcript from the Pretrial Conference is not yet available. However, at that conference, Defendants’ counsel, Mr. Shannon, represented that Defendants had considered raising the preemption defense for summary judgment, opening briefs for which were due December 19, 2019 (*see* Dkt. 106 at 2).

³ This is not the first time Defendants attempted to sneak a new affirmative defense into the case without the Court’s permission. Last year, Defendants included the affirmative defense of statute of limitations in their proposed amended counterclaims without notifying the Court or seeking leave to add that defense. While the Court allowed the amendment, it called Defendants’ conduct “somewhat surreptitious.” (Dkt. 85 at 7.)

II. ARGUMENT

Here, where the Court has issued a scheduling order and an amendment would violate a Court-Ordered deadline, “Rule 16(b)’s more stringent good cause standard supplants Rule 15(a)’s leave freely given standard.” *U.S. ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 192 (1st Cir. 2015) (citations omitted). “Rule 16(b)’s ‘good cause’ standard emphasizes the diligence of the party seeking the amendment.” *O’Connell v. Hyatt Hotels*, 357 F.3d 152, 155 (1st Cir. 2004). Under this inquiry, “[p]rejudice to the opposing party remains relevant but is not the dominant criterion.” *Id.* “‘Indifference’ by the moving party” may preclude leave to amend “irrespective of prejudice because such conduct is incompatible with the showing of diligence necessary to establish good cause.” *Id.* Further, where a “motion to amend is filed after the opposing party has timely moved for summary judgment, a [moving party] is required to show ‘substantial and convincing evidence’ to justify a belated attempt to amend a complaint.” *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215, 231 (1st Cir. 2005) (“*MEEI I*”) (quoting *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004)); *id.* (holding that the “district court did not abuse its discretion in determining that MEEI has failed to meet its burden of showing some valid reason for its neglect and delay”) (quotation and alteration omitted).

A. Preemption Is An Affirmative Defense That Should Have Been Pled

While not specifically called out in Rule 8(c), this Court and others have repeatedly held that preemption is an affirmative defense that must be pled. “[P]reemption is an affirmative defense as to which defendant bears the burden of proof.” *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 368 F. Supp. 3d 94, 115 (D. Mass. 2019) (Saylor, J.); *McLaughlin v. Harbor Cruises LLC*, No. 06-11299-GAO, 2009 WL 890099, at *2 (D. Mass. Mar. 31, 2009) (“regard[ing] the [preemption] argument as waived for not having been presented in a more timely fashion” because Defendant’s answer to the second amended complaint “[did] not assert preemption as an

affirmative defense”). “Ordinary preemption constitutes an affirmative defense and is based on the concept of supremacy of federal law over state and local regulations.” *Bd. of Selectmen of the Town of Grafton v. Grafton & Uptown R.R. Co.*, No. 12-cv-40164-TSH, 2013 WL 2285913, at *5 (D. Mass. May 22, 2013). “Preemption has been held to be an affirmative defense. *See* 5 Wright & Miller, *Federal Practice and Procedure: Civil 2d* § 1271, at 442 n. 51 (1990) (collecting cases).” *Williams v. Ashland Eng'g Co.*, 863 F. Supp. 46, 48 (D. Mass. 1994), *aff'd*, 45 F.3d 588 (1st Cir. 1995). “Normal ‘conflict’ preemption” is “an affirmative defense which defendant must plead and prove.” *Cambridge Literary Props., Ltd., v. W. Goebel Porzellanfabrik G.m.b.H. & Co. KG*, 510 F.3d 77, 100 n.22 (1st Cir. 2007) (Cyr, J. dissenting); *see Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393 (1987) (cases cannot be “removed to federal court on the basis of a federal defense, including the defense of pre-emption”).⁴ Indeed, the first case Defendants cite on preemption, *University of Colorado Foundation, Inc. v. American Cyanamid Co.* (Dkt. 221 at 50), calls it an affirmative defense: “As affirmative defenses, Cyanamid asserted that the doctrines of preemption by federal patent law, laches, and limitations under relevant statutes barred the University’s claims.” 196 F.3d 1366, 1370 (Fed. Cir. 1999).

B. Defendants Cannot Possibly Show Good Cause For Their Untimely Defense

The claims that Defendants now say are barred by preemption—unfair trade practices, conversion, and unjust enrichment—have been in the case since the original complaint, filed nearly three years ago. Defendants could have raised preemption any time since then, but chose not to. Moreover, Defendants’ counsel admitted at the Pretrial Conference that they have been

⁴ Other Circuits also have held that preemption is an affirmative defense. *See, e.g., Saks v. Franklin Covey Co.*, 316 F.3d 337, 350 (2d Cir. 2003) (preemption is an affirmative defense that is subject to waiver); *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018) (“Preemption is an affirmative defense that the defendant has the burden to prove.”); *Fifth Third Bank ex rel. Tr. Officer v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005) (“Federal preemption is an affirmative defense upon which the defendants bear the burden of proof.”).

considering a preemption defense for at least eight months (*i.e.*, since summary judgment), but chose not to reveal it until just last week.

To justify an untimely amendment, Defendants would need to show good cause. *D'Agostino*, 802 F.3d at 192. But here, Defendants have **no** cause, much less good cause, for failing to seek leave to add this defense years ago, or at the very least eight months ago, when they claim to have first considered the defense. Nor should Defendants' tactics of repeatedly trying to sneak new affirmative defenses into the case without the Court's permission be countenanced. While the Court allowed this approach once, the Court's admonition that Defendants' behavior was "somewhat surreptitious" (Dkt. 85 at 7) should have put them on notice not to repeat this behavior. This is not a *pro se* case. Defendants are represented by experienced counsel from a reputable firm. And their attempt to slip in new defenses on the eve of trial is inexcusable.

Courts have consistently rejected attempts to add such untimely defenses. *See, e.g., In re Cumberland Farms, Inc.*, 284 F.3d 216, 225 (1st Cir. 2002) (no abuse of discretion in denying a motion to amend where party "fail[ed] to raise it until the eve of trial, more than six months after Cumberland first asserted its set-off claim"). The First Circuit has "explicitly condemned a 'wait and see' approach to pleading whereby [movants] 'having the needed information, deliberately wait in the wings . . . with another amendment to a [pleading] should the court hold the first [pleading] was insufficient.'" *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 61 (1st Cir. 2018) (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 57 (1st Cir. 2008)) (ellipsis in original). Similarly, this Court has held a preemption affirmative defense waived as untimely when it was raised even earlier than on the eve of trial. *McLaughlin*, 2009 WL 890099, at *2 (preemption defense waived where belatedly raised in supplemental briefing before class certification).

Moreover, while no showing of prejudice is required in view of Defendants' indifference and gross delay, *O'Connell*, 357 F.3d at 154–55, there is no doubt that Astellas **would** be substantially prejudiced by allowing this last minute defense. If ImStem had raised the defense in a timely fashion, Astellas would have addressed the issue in discovery, on summary judgment⁵, and in its pretrial briefs. But by raising it at the last minute, without any notice, Defendants have deprived Astellas of any opportunity to address the issue. Such trial by ambush is precisely what the Federal Rules, this Court's Rules, and this Court's Orders are designed to prevent.

III. CONCLUSION

Astellas respectfully requests that the Court preclude Defendants from adding a new preemption affirmative defense on the eve of trial.

⁵ Defendants' preemption defense could have been disposed of on summary judgment because it lacks any substantive merit. Indeed, at least one of Defendants' cases held that state law claims of fraudulent transfer and unjust enrichment are **not** preempted. *Univ. of Colo.*, 196 F.3d at 1371 ("the fraudulent nondisclosure and unjust enrichment causes of action cover a broad range of conduct that does not bear on federal patent policies, and those causes of action are therefore not preempted by federal patent law"). Further, Defendants themselves asserted an unjust enrichment counterclaim based **solely** on inclusion of information in Astellas' patents. (Dkt. 91 at Countercl. ¶¶ 49-63.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent on August 20, 2020 to those identified as non-registered participants.

/s/ David P. Frazier

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